

104TH CONGRESS
2D SESSION

S. 2024

To amend the Public Health Service Act to provide a one-stop shopping information service for individuals with serious or life-threatening diseases.

IN THE SENATE OF THE UNITED STATES

AUGUST 2, 1996

Ms. SNOWE (for herself and Mrs. FEINSTEIN) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend the Public Health Service Act to provide a one-stop shopping information service for individuals with serious or life-threatening diseases.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. INFORMATION PROGRAM ON DRUGS FOR SERI-**
4 **OUS OR LIFE-THREATENING DISEASES.**

5 Section 402 of the Public Health Service Act (42
6 U.S.C. 282) is amended—

7 (1) by redesignating subsections (j) and (k) as
8 subsections (k) and (l), respectively; and

1 (2) by inserting after subsection (i), the follow-
2 ing new subsection:

3 “(j)(1) The Secretary, acting through the Director of
4 the National Institutes of Health, shall establish, main-
5 tain, and operate a program with respect to information
6 on research, treatment, detection, and prevention activities
7 relating to serious or life-threatening diseases and condi-
8 tions. The program shall, with respect to the agencies of
9 the Department of Health and Human Services, be inte-
10 grated and coordinated, and, to the extent practicable, co-
11 ordinated with other data banks containing similar infor-
12 mation.

13 “(2)(A) After consultation with the Commissioner of
14 Food and Drugs, the directors of the appropriate agencies
15 of the National Institutes of Health (including the Na-
16 tional Library of Medicine), and the Director of the Cen-
17 ters for Disease Control and Prevention, the Secretary
18 shall, in carrying out paragraph (1), establish a data bank
19 of information on clinical trials and treatments (including
20 drugs, biologicals, devices, and other therapies) with re-
21 spect to serious or life-threatening diseases and conditions.

22 “(B) In carrying out subparagraph (A), the Secretary
23 shall collect, catalog, store and disseminate the informa-
24 tion described in such subparagraph. The Secretary shall
25 disseminate such information through information sys-

1 tems, which shall include toll-free telephone communica-
2 tions, available to individuals with serious or life-threaten-
3 ing diseases and conditions, to other members of the pub-
4 lic, to health care providers, and to researchers.

5 “(3) The Data Bank shall include the following:

6 “(A) A registry of clinical trials (whether Fed-
7 erally or privately funded) of experimental treat-
8 ments (including drugs, biologicals, devices, and
9 other therapies) for serious or life-threatening dis-
10 eases and conditions under regulations promulgated
11 pursuant to sections 505 and 515 of the Federal
12 Food, Drug, and Cosmetic Act that provides a de-
13 scription of the purpose of each experimental drug
14 protocol, either with the consent of the protocol
15 sponsor, or when a trial to test efficacy begins. In-
16 formation provided shall include eligibility criteria, a
17 description of the location of trial sites, and a point
18 of contact for those wanting to enroll in the trial,
19 and shall be in a form that can be readily under-
20 stood by members of the public. Such information
21 must be forwarded to the Data Bank by the sponsor
22 of the trial not later than 21 days after approval by
23 the Food and Drug Administration.

1 “(B) Information pertaining to experimental
2 treatments for serious or life-threatening diseases
3 and conditions that may be available—

4 “(i) under a treatment investigational new
5 drug application that has been submitted to the
6 Food and Drug Administration pursuant to
7 part 312 of title 21, Code of Federal Regula-
8 tions;

9 “(ii) as a Group C cancer drug; or

10 “(iii) under an exemption for devices
11 for investigational use pursuant to part
12 812 of title 21, Code of Federal Regula-
13 tions.

14 The Data Bank shall also include information
15 pertaining to the results of clinical trials of
16 such treatments, with the consent of the spon-
17 sor, including information concerning potential
18 toxicities or adverse effects associated with the
19 use or administration of such experimental
20 treatment.

21 “(4) For the purpose of carrying out this subsection
22 there are authorized to be appropriated such sums as may
23 be necessary.”.

○